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16. ABSTRACT

An overview of the air pollution quality assurance program as implemented by EMSL/RTP is presented. The discussion includes method standardization operations for both ambient air and stationary source measurements, the quality assurance audit program, the ambient air equivalency program, standard laboratory operation, and the development of air pollution reference materials. In addition, the new EPA mandatory Quality Assurance program is discussed.

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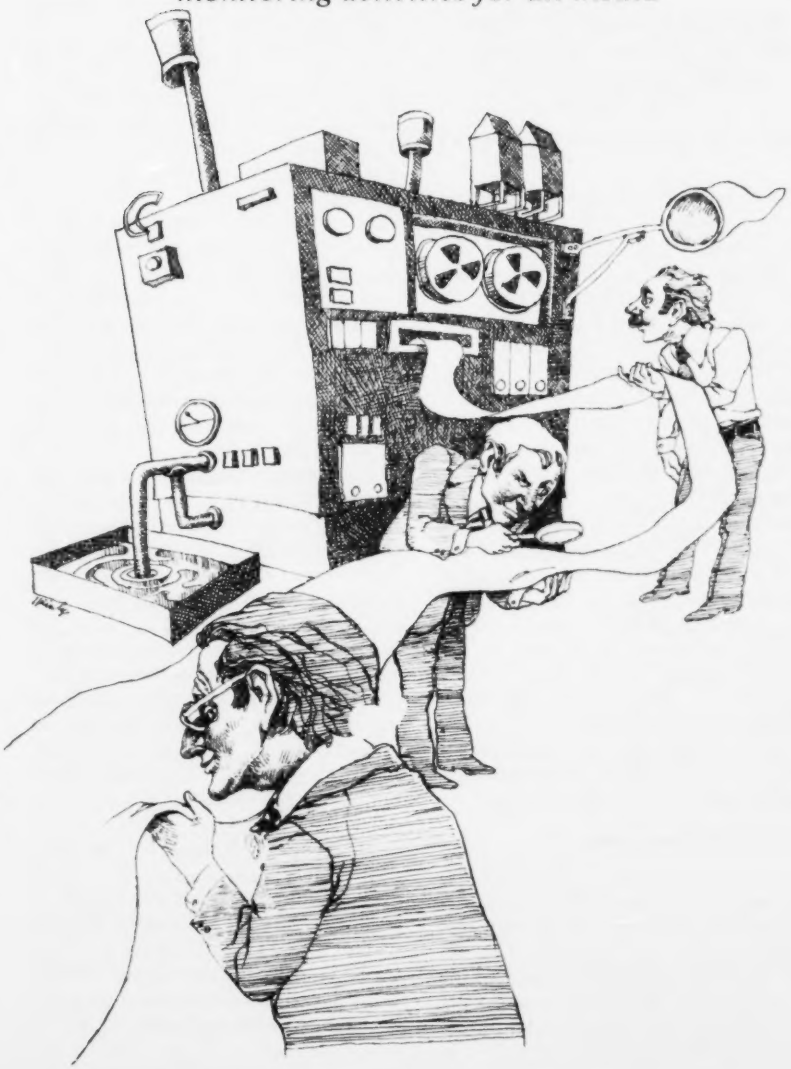
Quality assurance update

EPA laboratory directors present overviews of the air and water QA programs. EPA instituted a new policy in May 1979 which mandated that a comprehensive QA effort be applied to all EPA funded or required monitoring activities for all media



The Environmental Monitoring Systems Laboratory at Research Triangle Park, N.C. (EMSL/RTP) is the laboratory within EPA responsible for developing and implementing a nationwide quality assurance program for the measurement of air pollutants both in ambient air and in sources of emissions. The term "quality assurance" has been interpreted a number of ways and is sometimes used interchangeably with the term "quality control", so it would be helpful here to define quality assurance as it is employed by EMSL/RTP. We view quality control as those internal operations performed during the measurement process (e.g., periodic calibrations, duplicate checks, split samples, spiked samples, etc.) to document the quality of data.

Quality assurance is composed of those activities performed on a more occasional basis, usually by a person outside of the normal operations, to gain an independent assessment of monitoring operations and data assessment (e.g., on-site system surveys, independent performance audits, interlaboratory comparisons, and split-sample analysis). In essence, quality assurance is a system of activities to provide assurance that quality control systems are performing adequately.

The tools needed to conduct both the internal and external programs must be developed and made available to the monitoring community—such tools as standardized methods, calibration materials, standard reference materials, a standards laboratory, audit services, training, QA guidelines, and a commitment by management that quality data are essential to conduct successful quality control and quality assurance programs. Therefore we at EMSL/RTP view the EPA air pollution quality assurance program as the development and distribution of the tools needed to improve and document the quality of air pollution measurements. Quality assurance is also concerned with establishing and assessing comparability and interrelatability of data collected by numerous public and private organizations.

The EMSL/RTP policy

Considered by itself, air pollution monitoring data is neither "good nor bad". The quality of the data (i.e.,

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"precision, accuracy, and completeness") is either known or unknown. Data of unknown quality is relatively useless for setting standards, developing control strategies or demonstrating compliance with an existing standard. The desired data quality may vary depending on the intended use of data; hence, the objectives of any air monitoring effort will immediately determine the data quality requirements and also dictate the degree of quality assurance activities necessary to achieve the desired data quality.

For example, data of high quality is necessary to support an enforcement action or to support a health effects study while data of lesser quality may be acceptable for air pollution trend monitoring purposes. Management has the prime responsibility for setting the monitoring objectives since they ultimately will use the data for its intended purpose. Difficulties arise when data collected to meet one monitoring objective are used by others with different objectives without regard for the quality of the data.

The user of the data has the responsibility to ascertain the quality of the data and use it properly when making air resource management decisions; the quality assurance program simply makes known the quality of the data and does not of itself make data "good or bad". Often, data of unknown quality is worse than no data at all since erroneous and very costly compliance programs could possibly be mandated unnecessarily.

Sometimes quality assurance is incorrectly viewed as a policing action whose only purpose is to harass monitoring operations. On the contrary, the basic goal of the air pollution quality assurance program is to *help* people conducting monitoring activities establish the quality of their data, point out possible problem areas, and to make their measurements as precise and accurate as needed to attain the monitoring objectives. It is not the intent of the QA program to embarrass people who are having monitoring problems but rather to assist them in correcting problems as efficiently and quietly as possible.

Often, we are asked to look at historical air pollution data and make estimates of its quality in the absence of quality assurance data. This is at best very difficult and more often than not impossible. This subject is discussed here to make managers aware of the fact that if proper QA activities are not employed at the time of the monitoring operation, they should be suspicious of anything stated or written about data quality and usefulness.

Retrospective qualification of data has occurred in the past due to the lack of a nationwide and uniform quality assurance program, but times have changed. EPA has recently published new air pollution monitoring, data reporting, and quality assurance regulations in support of State Implementation Plans and also adopted a policy to include a mandatory quality assurance program in all EPA research and monitoring activities. These activities are discussed later in this paper and should alleviate problems in qualifying historical data.

QA costs are often thought of as a necessary evil that subtracts from the resources available to conduct the monitoring activity thereby resulting in the collection of less data. It is our view that it is more expensive in the long run to produce more data of unknown quality than it is to implement a concurrent QA program and accept less data than is properly qualified.

"It has been our experience that we can often get along with less data, provided it is of good quality."
EPA's Hauser

When data of unknown quality becomes suspect, it is often discarded and the monitoring effort is wasted. As a result not only are the resources expended for the monitoring effort lost, but additional resources must be found to repeat the effort if necessary.

We can no longer afford to gather data of unknown quality for it is a waste of dollars and manpower. It has been our experience that we can often get along with less data, provided it is of good quality. A monitoring program should be carefully planned to include a proper study design, proper sampling and analytical techniques, statistically correct data validation and reporting procedures, and internal and external quality assurance programs as described above. Unless all of these components are properly addressed before monitoring actually starts, the project should not be initiated. This is true for both ambient air monitoring and source emission monitoring.

EMSL/RTP programs

As stated earlier, EMSL/RTP is the lead laboratory within EPA to develop and implement an air pollution quality assurance program. The objective of this program is to provide the reference or standard monitoring methods and associated standard reference materials to conduct nationwide performance audits and to develop guideline and technical assistance documents needed for internal quality control programs and on-site system surveys.

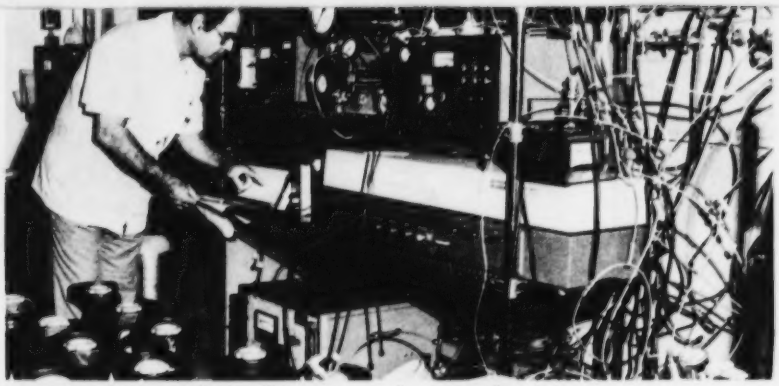
These are the major items needed by the operational and research monitoring programs in the acquisition of accurate and legally defensible ambient and source air quality data. Emphasis is given to those reference methods, quality control procedures, standard reference materials, and guideline documents needed to enforce standards and regulations now in existence and being planned for adoption by EPA.

Reference and standard methods (for ambient air and sources). EMSL conducts a vigorous methods standardization program which involves screening and selection of manual or continuous methods suitable for monitoring a specific pollutant, an in-depth examination of a selected method in one laboratory, reporting the results of the evaluation, and the preparation of a method write-up in suitable format. Estimates of the precision and accuracy of the method are developed through collaborative tests among serveral laboratories or by other means, and final reports and recommendations on the use of the method are published.

Finally, a federal reference method is prepared and published in the *Federal Register* if warranted. This process is followed for both ambient air and source emission methods. A listing of the methods that either are or have been under investigation and numerous reports concerning methods standardization activities are available from EMSL/RTP.

Equivalency program (for ambient air measurements). The equivalency program is a basic and integral part of the overall QA program that establishes the air monitoring methodology to be used in air monitoring programs established by state and local air pollution agencies in conjunction with State Implementation Plans (SIP). Essentially this program mandates which methods, either continuous or manual, are to be used in the SIP monitoring program to measure those pollutants for which air quality standards have been set.

A Federal Reference Method (FRM) has been established for each of these pollutants, but EPA recognizes that more than one method can be used to measure an air pollutant satisfactorily. In order for a candidate method to be declared an equivalent method, it must be compared with the FRM



Instrumentation. *Analyzing QA compressed gas samples*

and meet a number of requirements specified in EPA regulations (40 CFR 53). If a method is declared equivalent, it enjoys the same regulatory status as the FRM.

As published in 40 CFR 53, the FRMs for CO, O_3, HC, and NO_2 consist of a measurement principle, a set of performance specifications, and a calibration procedure. Consequently, there are numerous ways an instrument manufacturer may choose to build an instrument within these constraints. For this reason, it is possible to have a number of different instrumental configurations for a single FRM, each of which would receive a separate FRM designation for measuring a single pollutant. To date, 22 reference methods and 17 equivalent methods have been approved for SIP monitoring activities. A list of these methods can be obtained from EMSL/RTP or any EPA regional office.

On site system survey. Laboratory and monitoring site evaluation by actual inspection is an important feature of the Agency's air pollution quality assurance program. On-site system surveys are a very effective means of evaluating the competency of laboratories making air pollution measurements and provide valuable information regarding areas and programs that need improvement. The techniques and methodologies for conducting laboratory and monitoring site evaluations have been developed and formalized so that uniform evaluation procedures can be used nationwide.

Quality assurance audits: ambient air. Since 1972 the EMSL/RTP has provided an ambient air Performance Audit Program to various monitoring groups throughout the U.S. and in several foreign countries. The program participants analyze a set of samples of unknown concentration for a particular pollutant and send the results to EMSL/RTP for statistical analysis.

The participants are then notified of their individual performance as compared to the known concentrations and to the performance of the rest of the participants in the survey. The audit program is only one part of an external quality assurance program, so the results should not be construed as an absolute indicator of data quality. Used along with information obtained from an internal quality control program, however, the conclusions can be quite meaningful.

The purposes of the audit program are twofold. The first is to give agencies that participate a means of rapid self-evaluation of the specific monitoring operation under their purview. The second objective is to provide EPA with a continuing index of the validity of data being reported to air quality data banks.

Audits are conducted routinely for CO, SO_2, NO_2, sulfate-nitrate ($SO_4^=$, NO_3^-), Pb, and hi-volume flow measurements. The number of monitoring groups participating in this program range from 71 for the sulfate and nitrate audits to 216 for the hi-vol flow audits. Summary publications have been published on the results of the audits and they are available from EMSL/RTP.

Quality assurance audit: source measurements. To ensure that good quality data is obtained with EPA reference test methods, EMSL/RTP conducts nationwide surveys on a semi-annual basis to determine the ability of laboratories to analyze reference materials representative of stack samples. For example, the initial survey of Method 6 (SO_2) showed that 50% of the participants reported a value within 2.2% of the true sample concentration.

In contrast, the initial survey of Method 7 (NO_x) showed that 50% of the participants were within 15% of the true value. Subsequent surveys show a definite improvement in the ability of labs to use these methods, attributable in part to participation in these surveys. Plans are underway within EMSL to expand this program and to extend it to the evaluation of in-stack continuous emission monitors.

Development of quality control materials. EMSL/RTP operates an intensive program to develop quality control materials for use in both ambient air and stationary source measurements systems. After development, these materials are used in the EMSL audit programs and are made available to the monitoring community for use in their measurement activities. Examples of these materials include standard reference samples (traceable to NBS standards) that are used for the blind audits of monitoring activities, quality control check samples for use in a laboratory's internal quality control program, and devices to check air sampling flow rates. Part of these development activities are accomplished through an Interagency Agreement with the National Bureau of Standards.

Standards laboratory operations. In implementing the new ambient air quality monitoring provisions (discussed later in the paper), agencies will be required to document quality control data and show traceability of their quality assurance materials to NBS reference materials. To help the state, local, and regional air monitoring agencies meet the new requirements, EMSL has established a standards lab and the following services are offered. Where applicable, all verifications are referenced to NBS standard reference materials.

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EPA's Hauser

- verification of compressed gas standards used for calibration, span checks or audits of air quality analyzers (NO, NO_2, SO_2, CO, CO_2, CH_4, hydrocarbons)
- verification of permeation tube rates (gravimetric or direct comparison with SRM)
- verification of flow measuring devices (mass flowmeter, hi-vol orifice meters)
- verification of outputs of calibration or audit devices (SO_2, ozone, NO, NO_2, CO, CO_2, CH_4, hydrocarbons)
- verification of static audit or calibration standards (nitrite solution, potassium tetrachloromercurate sulfite freeze-dried powders; sulfate and lead on glass-fiber filter strips)
- other special analyses are available upon request.

Sample repositories. EMSL maintains a quality assurance sample re-

pository of both ambient air and stationary source reference samples. For the measurements of pollutants in ambient air, samples are available to assist in the measurement of NO_2, SO_2, NO, CO, and CH_4 in the gaseous state and for sulfate, nitrate, NH_4^+, Pb, and As in air particulate matter. For the measurement of pollutants in stationary sources, critical orifice devices are available to check the volume meter calibration for the Method 5 sampling train and liquid samples are available to check performance on the analytical portion of Methods 6 (SO_2) and Method 7 (NO_x). Gases at source level concentrations for use in continuous monitors are available for NO, NO_2, SO_2, CO_2 and O_2.

In addition, a selection of 16 organic materials are also maintained at source level concentrations. This repository is a dynamic operation. That is, as samples are expended, they are replaced; as new materials are developed, they are incorporated. A listing of all current materials contained in the repository is available upon request.

"The goal of the QA program is to obtain scientifically valid, defensible data of known precision and accuracy to fulfill the Agency's responsibility to protect and enhance the nation's environment."
EPA Policy, May 1979

Quality assurance guideline documents. QA guideline documents have been prepared and are continually reviewed and updated for all aspects of the total monitoring system (including development of a QA plan, management, sampling, analysis, and data handling) for ambient air quality criteria pollutants, non-criteria pollutants, stationary source pollutants, lead and phosphorus in gasoline, and mobile source pollutants.

In addition, a three volume Quality Control Handbook has been developed. Volume I addresses the Quality Assurance Principles of Air Pollutant Measurement Systems; Volume II addresses ambient air pollutant monitoring, and Volume III deals with source pollutant monitoring. These volumes are prepared in loose-leaf format and are continuously updated as new information becomes available.

QA program is mandatory now

In May 1979, EPA administrator Douglas M. Costle promulgated a quality assurance policy statement for the Agency. Agency *policy* now requires participation in an Agency-wide quality assurance program by *all* EPA regional offices, program offices, research laboratories, and those monitoring and measurement efforts supported or mandated through contracts, regulation or other formalized agreements. This requirement includes quality assurance programs for states which will be cooperatively developed with them and implemented through the regional offices.

Performance audits. *Developing instrumentation for on-site audits*

The Office of Research and Development within EPA (of which EMSL/RTP is a part) has been delegated primary responsibility for developing the national quality assurance program and directing and coordinating its implementation. The goal of the program is to obtain scientifically valid, defensible data of known precision and accuracy to fulfill the Agency's responsibilities to protect and enhance the nation's environment. In summary, the QA program will be compulsary for *all* Agency-supported or required environmentally-related monitoring and measurements which generate data for EPA use.

The mandatory quality assurance program will impact EPA's extramural monitoring and research program. Over the past several years, the EPA has become more and more dependent on extramural projects to provide the environmental measurements used as a foundation for our standards, regulations and decisions. In order to assure that all environmental measurements accomplished through extramural funding result in usable data of known quality, Costle made mandatory the inclusion of the following QA requirements in all EPA grants, contracts, cooperative agreements, and interagency agreements that involve environmental measurements.

- A written QA plan should be developed that includes the oversight role of management, identification of personnel responsible for the QA program, proper sample collection, use of approved measurement techniques, calibration standards and their verification, internal quality control practices, and appropriate data management controls. Pre-award information can be limited to that required to evaluate capabilities. The specific QA plan may be developed and subsequently approved by EPA after award of funds.
- A cost estimate associated with the QA program in terms of percentage of overall project cost shall be provided. Normally a minimum of 10-30% of the estimated sample collection and analyses costs will be necessary for adequate quality control.
- As a condition of award, acceptable performance must be demonstrated on audit samples, when available and where applicable, and throughout duration of contract/grant.
- Provision shall be made for on-site laboratory and/or field-site evaluation at option of the Project Officer for a performance evaluation and for documentation that all equipment and supplies necessary for successful completion of the project are available.
- Documented quality control performance will be submitted with the final report and otherwise as required by the Project Officer. Criteria and guidelines providing further details and steps to implement these general QA requirements will be forthcoming from EPA.

QA support for new monitoring regs

On May 10, 1979 EPA promulgated new regulations (*Federal Register* **44**, p. 27558) for ambient air quality monitoring and data reporting in support of State Implementation Plans. The national program managership for

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these regulations resides in the Monitoring and Data Analysis Division (MDAD) of EPA's Office of Air Quality Planning and Standards under the direction of Robert Neligan.

Appendices A and B of these regulations deal with the QA requirements for State and Local Air Monitoring Stations (SLAMS) and Prevention of Significant Deterioration (PSD) air monitoring respectively. In developing these QA requirements, EMSL/RTP took the position that a satisfactory quality assurance system consists of two distinct and equally important functions.

One function is the assessment of the quality of the monitoring data by estimating their precision and accuracy. The other function is the control, and improvement, of the monitoring data quality by implementation of quality control policies, procedures, and corrective actions as required. These two functions form a control loop: When the assessment function indicates that the data quality is inadequate, the control effort must be increased until the data quality is acceptable.

In Appendices A and B of the regulations, the assessment procedures are specified explicitly to provide uniformity in the assessment and reporting of data quality among all SLAMS and PSD networks. In contrast, the control and corrective action function encompasses a variety of policies, procedures, specifications, standards, and corrective measures which have varying effects on the resulting data quality. The selection and degree of specific control measures and corrective actions used depend on a number of factors such as the monitoring methods and equipment used, field and laboratory conditions, the objectives of the monitoring, the level of the data quality needed, the expertise of assigned personnel, the cost of control procedures, and pollutant concentration levels.

Because quality control requirements can and do differ from agency to agency, they are specified in Appendices A and B in general terms to allow each state to develop a quality control system which is most effective for its own circumstances for both SLAMS and PSD monitoring. The monitoring regulations and associated quality assurance requirements are much too lengthy and involved to present in this overview paper. However, two recent EMSL/RTP activities in support of the regulations are of interest and are presented here.

First, regional workshops were conducted jointly with MDAD. Members of the EMSL/RTP and MDAD staff presented workshops in each of the 10 EPA regional offices between April 9 and June 21, 1979. Each state and many local air monitoring agencies were represented and thoroughly briefed on the content, intent, and requirements of the new regulations. The major topics covered were:

- highlights of the regulations
- significant milestones for implementation of regulations
- major comments on the proposed regulations
- QA for SLAMS and PSD monitoring
- precision and accuracy calculations
- ambient air quality monitoring methodology to be used
- network design for SLAMS and NAMS
- probe siting criteria for ambient air quality monitoring
- annual SLAMS air quality information to be reported to EPA
- uniform air quality index and daily reporting
- requirements for a revised State Implementation Monitoring Plan
- NAMS network.

Copies of the briefing materials are available from MDAD.

Second, EMSL/RTP has established a major QA support contract to provide quality assurance technical assistance to state/local air pollution control agencies in the implementation of quality assurance requirements of the new regulations. Support will be provided in six technical service areas as listed below:

1. workshops on audits
2. QA guideline development
3. audit system verification
4. audit materials analysis and traceability
5. QA technical assistance
6. required performance audits when states lack resources.

Monitoring data validation & storage

As stated earlier, the MDAD is the National Program Manager for the monitoring and data requirements for the National Air Monitoring Stations (NAMS) and SLAMS. MDAD has published a draft NAMS Management Plan and issued a guideline document entitled "Screening Procedures for Ambient Air Quality Data". These documents and other information, available directly from MDAD, delineate the data information procedures needed to store air quality data in the SAROAD system. Requests for information concerning these activities should be directed to Robert Neligan for MDAD, Office of Air Quality Planning and Standards (MD-14), EPA, RTP, N.C. 27711.

Last word

Since EPA is basically a regulatory agency, the data used by the Agency to develop strategies, set standards, and/or develop regulations, as well as the monitoring data generated to demonstrate compliance with the standards or regulations, must be known, well documented, and of high quality. It is my belief that EPA has made great strides in these two areas in the past year through the establishment of a mandatory quality assurance program on all monitoring and research efforts and the promulgation of the new air pollution monitoring and quality assurance regulations.

Coupling these two activities will close the loop and assure that both the data used to set standards and the data used to judge compliance with standards will be of high quality. Only in this way can the Agency gain the credibility it needs to attain its main responsibilities to protect and enhance the nation's environment.

Numerous references have been made throughout this paper that materials are available from EMSL/RTP. I encourage you to contact the following people directly for information and publications as necessary.

Dr. John B. Clements—director, Quality Assurance Division, EMSL/RTP

Mr. Thomas A. Clark—chief, Performance Evaluation Branch, QAD, EMSL/RTP

Mr. Larry Purdue—chief, Methods Standardization Branch, QAD, EMSL/RTP

Mr. Rodney Midgett—chief, Source Branch, QAD, EMSL/RTP

Address and telephone number for the Quality Assurance Division (QAD) are: Environmental Protection Agency, Environmental Monitoring Systems Laboratory, Quality Assurance Division (MD-77), Research Triangle Park, N.C. 27711. Telephone: 919-541-2195 or FTS 629-2195.

Thomas R. Hauser *is the director of the Environmental Monitoring Systems Laboratory located at the Research Triangle Park, N.C. He is responsible for*

developing and implementing a nationwide quality assurance program for the measurement of air pollutants both in ambient air and in sources of emissions. In addition, EMSL/RTP conducts specialized field monitoring and analytical programs to gather information in support of developing air pollution strategies, establishing regulations, supporting health effect studies, and/or measuring toxic substances. For the past 24 years, Dr. Hauser has been employed in the Federal Air Pollution Control Program and has published numerous technical articles concerned with the development and evaluation of analytical methodology for the analysis of air pollutants as well as review papers on EPA monitoring activities.